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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/627,829	LEHRER ET AL.	
	Examiner	Art Unit	
	David J Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-17 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-21 are pending in the application.

[2] Applicants' response, filed November 19, 2004, to the restriction requirement mailed May 19, 2004, is acknowledged.

[3] Applicants' amendment to the specification, filed November 19, 2004, is acknowledged.

Election/Restriction

[4] Applicants' election of Group IV, claims 13-17 and 19-21 and Group a), SEQ ID NO:16, filed November 19, 2004, is acknowledged.

[5] Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

[6] Claims 1-12 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

[7] Claims 13-17 and 19-21 are being examined on the merits only to the extent the claims read on the elected subject matter.

Claim to Priority

[8] Applicants' claim for domestic priority under 35 USC §§ 120 and 121 as set forth in the amendment to the specification, filed November 19, 2004, is acknowledged.

[9] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §§ 120 and/or 121 as follows: the filing date of parent application 09/128,345 has not been listed in the priority claim filed November 19, 2004. According to PTO records, the filing date of application 09/128,345 is August 03, 1998.

Information Disclosure Statement

[10] The examiner can find no information disclosure statement (IDS) filed in the instant application. If the examiner has inadvertently overlooked an IDS that has been filed in the instant application, applicants are requested to notify the examiner in the response to this Office action.

Drawings

[11] The drawings are objected to as Figure 1 is incomplete as the Y-axis is not labeled. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Sequence Compliance

[12] The instant application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicants' attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicants should identify nucleotide sequences of at least 10 nucleotides and amino acid sequences of at least 4 amino acids in the specification by a proper sequence identifier, i.e., "SEQ ID NO:" (see MPEP 2422.01). If these sequences have not been listed in the computer readable form and paper copy of the sequence listing, applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See particularly pp. 18-20, 22, 34, 45-48 of the specification and Figures 7-8 and 10.

Specification/Informalities

[13] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: --Method of Treating or Preventing a Microbial Infection Using Protegrin Peptides--.

[14] The abstract filed July 24, 2003 is objected to as it is not a single paragraph. The abstract should be a single paragraph. Correction is required. See MPEP § 608.01(b).

[15] The use of the trademark "E-Toxate™" has been noted in this application (p. 38, line 34). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

[16] Claim 13 is objected to as being dependent upon non-elected claim 1. It is suggested that, for example, applicants incorporate the limitations of claim 1 into claim 13.

[17] Claims 13 and 17 are objected to as reciting non-elected subject matter. The elected invention is a method for treating or preventing a microbial infection. Claims 13 and 17 additionally recite subject matter drawn to a method for treating or preventing a viral infection. It is suggested that applicants amend the claims so that the claims no longer recite non-elected subject matter.

[18] Claims 15 and 19 are objected to in the recitation of "*E. coli*," "*L. monocytogenes*," "*B. subtilis*," "*S. typhimurium*," "*S. aureus*," "*P. aeruginosa*," and "*E. faecalis*." To avoid confusion, abbreviations should not be recited in the claims without

at least once reciting the entire phrases for which the abbreviations are used.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[19] Claims 13-17 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an *in vitro* method of inhibiting growth of *L. monocytogenes, C. albicans, P. aeruginosa, K. pneumoniae, S. typhimurium, S. aureus, H. capsulatum, M. avium-intracellulae, M. tuberculosis, V. vulnificus, E. coli, C. trachomatis, T. pallidum, N. gonorrheae, T. vaginalis,* or *E. faecalis* by administering to the cells the peptide of SEQ ID NO:16, 17, or 18, does not reasonably provide enablement for a method of treating or preventing a microbial infection in vivo in any subject by administering any compound of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are

summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

(A) The breadth of the claims: Claims 13 (claims 20-21 dependent therefrom), 14-17, and 19 are so broad as to encompass a method of treating or preventing all microbial infections (optionally limited to those recited in claims 14-17 and 19) in any subject including human subjects by administering any of the compounds broadly encompassed by claim 1. The scope of claimed methods is not commensurate with the enablement provided by the disclosure with regard to the microbial infection that can be treated or prevented, the ability to *prevent* a microbial infection, the subjects that can be treated, and the compounds that are employed in the method. In this case, the specification is enabling only for an *in vitro* method of inhibiting growth of *L. monocytogenes, C. albicans, P. aeruginosa, K. pneumoniae, S. typhimurium, S. aureus, H. capsulatum, M. avium-intracellulae, M. tuberculosis, V. vulnificus, E. coli, C. trachomatis, T. pallidum, N. gonorrheae, T. vaginalis,* or *E. faecalis* by administering to the cells the peptide of SEQ ID NO:16, 17, or 18.

(B) The nature of the invention: Applicants' invention is the discovery of specific peptides that have antimicrobial activity in cultured cells (see particularly pp. 18-22 and 32-62). However, the claimed invention is not so limited and broadly encompasses a method of treating or preventing microbial infection in subjects including humans by administering a vast number of peptides as encompassed by the formula of claim 1.

(C) The state of the prior art; (D) The level of one of ordinary skill; and (E) The level of predictability in the art: Based on the disclosure of the specification and the prior art, it is highly unpredictable as to whether a skilled artisan would treat or prevent any microbial infection *in vivo* using the broad scope of recited peptides. Neither the specification nor the prior art provide an indication that all recited peptides would have inhibitory activity against any microbe *in vitro* or *in vivo.* One of skill in the art would recognize that *in vitro* results suggesting a specific peptide has antimicrobial activity in cultured cells against a single microbe cannot be extrapolated to similar results *in vivo* against any microbial infection, even microbes of the same genus. Applicants' own specification provides evidence of such unpredictability as the specification discloses (p. 36, lines 15-17) the peptides, while being active against *V. vulnificus,* were inactive against *V. cholerae,* thus providing evidence that even among microbes of the same genus, a peptide effective against one member, may not be effective against other members of that genus. Also, even if a peptide was shown to effective against a single microbe, the concentration of peptide disclosed as being effective against that microbe is not necessarily sufficient to provide the same result against other microbes. One of skill in the art would also recognize the high level of unpredictability in applying *in vitro*

experimental results to a living organism, *e.g.,* a human subject. Such results are highly empirical and *in vitro* results demonstrating efficacy of a specific peptide against a particular microbe do not necessarily correlate with those that may be obtained *in vivo.* The specification acknowledges such unpredictability by stating, "the effectiveness of these peptides as antimicrobials depends on the nature of the target organism and on the test conditions" (p. 41, lines 7-9). Regarding the peptide that is used in the claimed method, it is noted that the amino sequence of a therapeutic peptide determines the peptide's therapeutic and physiological properties. Predictability of which changes can be tolerated in a peptide's amino acid sequence and obtain the desired activity/utility requires a knowledge of and guidance with regard to which amino acids in the therapeutic peptide's sequence, if any, are tolerant of modification and which are conserved (*i.e.*, expectedly intolerant to modification), and detailed knowledge of the ways in which the peptide's structure relates to its function. The positions within a therapeutic peptide's sequence where modifications can be made with a reasonable expectation of success in obtaining a peptide having the desired activity/utility are limited and the result of such modifications is highly unpredictable. In addition, one skilled in the art would expect any tolerance to modification to diminish with each further and additional modification, *e.g.,* multiple substitutions. The unpredictability is further compounded when one considers that the therapeutic effect of any compound is also dependent not only upon the structure of the peptide, but on additional factors, such as formulation of the peptide, dosage of the peptide, and route of administration.

(F) The amount of direction provided by the inventor and (G) The existence of working examples: The specification provides working examples of the use of the peptides of SEQ ID NO:16, 17, or 18 for the *in vitro* inhibition of microbial growth (see particularly pp. 35-62 of the specification). The specification fails to provide even a single working example of a method for treating or preventing a microbial infection in an *in vivo* setting. While the peptides of SEQ ID NO:16, 17, and 18 appear to have been effective against certain microbes *in vitro,* there is no guidance provided as to the effects of all peptides as encompassed by claim 1 on microbes *in vitro* or *in vivo.* While methods of producing variant peptides were known at the time of the invention, the specification fails to provide guidance regarding those amino acids of the peptides of SEQ ID NO:16, 17, and 18 that are required for antimicrobial activity such that one of skill could determine which of those peptides as broadly encompassed by claim 1 would or would not be effective for treatment of or have a prophylactic effect against a microbial infection. Moreover, the specification fails to provide guidance regarding a *specific* formulation, dosage, and/or route of administration of the peptide against a specific microbe that is expected to provide the desired result of treating or preventing a microbial infection.

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: At the time of the invention, it was not routine in the art to generate all peptides as broadly encompassed by claim 1 to screen for those that have an antimicrobial effect against all microbes both *in vitro* and *in vivo.*

In view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[20] Claims 13-17 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of US Patent

[20] Claims 13-17 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 34 of US Patent 5,804,558 (the '558 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of the instant application is generic to all that is recited in claim 34 of the '558 patent. That is, claim 13 is anticipated by claim 34 of the '558 patent. Alternatively, claims 14-17 and 19-21 cannot be patentably distinct over claim 34 of the '558 patent when there is a specifically disclosed embodiment in the '558 patent that supports claim 34 of that patent and falls within the scope of claims 14-17 and 19-21 herein because it would have been obvious to one of ordinary skill in the art to modify the method of claim 34 by selecting a specifically disclosed embodiment that supports that claim, *i.e.,* the method of claim 13, wherein the microbial infection is a bacterial infection, optionally wherein the bacteria are those recited in claims 15-17 and 19 of the instant application, and wherein the peptide is administered topically or prophylactically (see columns 4, 18, and 22 of the '558 patent). One of ordinary skill in the art would have been motivated to do this because those

embodiments are disclosed as being preferred embodiments within claim 34 of the '558 patent.

[21] Claims 13-17 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-42 of US Patent 5,994,306 (the '306 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of the instant application is generic to all that is recited in claims 37-42 of the '306 patent; claim 14 is generic to all that is recited in claims 38 and 40-41 of the '306 patent; and claim 19 is generic to all that is recited in claim 38 of the '306 patent. That is, claim 13 of the instant application is anticipated by claims 37-42 of the '306 patent; claim 14 is anticipated by claims 38 and 40-41 of the '306 patent; and claim 19 is anticipated by claim 38 of the '306 patent. Alternatively, claims 15-17 and 20-21 cannot be patentably distinct over claims 37, 39, and 42 of the '306 patent when there is a specifically disclosed embodiment in the '306 patent that supports claims 37, 39, and 42 of that patent and falls within the scope of claims 15-17 and 20-21 herein because it would have been obvious to one of ordinary skill in the art to modify the method of claims 37, 39, and 42 by selecting a specifically

disclosed embodiment that supports those claims, *i.e.,* the method of claim 37, wherein the microbial infection is a bacterial infection, optionally wherein the bacteria are those recited in claims 15-17 of the instant application, and wherein the peptide is administered topically or prophylactically (see columns 4-6 and 25 of the '306 patent). One of ordinary skill in the art would have been motivated to do this because those embodiments are disclosed as being preferred embodiments within claims 37, 39, and 42 of the '306 patent.

[22] Claims 13-17 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of US Patent 6,025,326 (the '326 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of the instant application is generic to all that is recited in claims 1-9 of the '326 patent. That is, claim 13 of the instant application is anticipated by claims 1-9 of the '326 patent. Alternatively, claims 14-17 and 19-21 cannot be patentably distinct over claims 1-9 of the '326 patent when there is a specifically disclosed embodiment in the '326 patent that supports claims 1-9 of that patent and falls within the scope of claims 14-17 and 19-21 herein because it would

have been obvious to one of ordinary skill in the art to modify the methods of claims 1-9 by selecting a specifically disclosed embodiment that supports those claims, *i.e.,* the method of claim 1 of the '326 patent wherein the oral mucositis is caused by a bacterial infection, optionally wherein the bacteria are those recited in claims 15-17 of the instant application, and wherein the peptide is administered topically or prophylactically (see columns 5-6 and 19-21 of the '326 patent). One of ordinary skill in the art would have been motivated to do this because those embodiments are disclosed as being preferred embodiments within claim 1 of the '326 patent.

[23] Claims 13-17 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-19, 23, and 25-29 of US Patent 6,043,220 (the '220 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of the instant application is generic to all that is recited in claims 15-19, 23, and 25-29 of the '220 patent; claim 14 is generic to all that is recited in claims 16-19 and 26-29 of the '220 patent; and claim 19 is generic to all that is recited in claims 16 and 26 of the '220 patent. That is, claim 13 of the instant application is anticipated by claims 15-19, 23, and

25-29 of the '220 patent; claim 14 is anticipated by claims 16-19 and 26-29 of the '220 patent; and claim 19 is anticipated by claims 16 and 26 of the '220 patent. Alternatively, claims 15-17 and 20-21 cannot be patentably distinct over claims 15-19, 23, and 25-29 of the '220 patent when there is a specifically disclosed embodiment in the '220 patent that supports claims 15-19, 23, and 25-29 of that patent and falls within the scope of claims 15-17 and 20-21 herein because it would have been obvious to one of ordinary skill in the art to modify the methods of claims 15-19, 23, and 25-29 by selecting a specifically disclosed embodiment that supports those claims, *i.e.,* the methods of claims 15, 23, and 25 wherein the microbial infection is a bacterial infection, optionally wherein the bacteria are those recited in claims 15-17 of the instant application, and wherein the peptide is administered topically or prophylactically (see columns 4, 6, and 21-23 of the '220 patent). One of ordinary skill in the art would have been motivated to do this because those embodiments are disclosed as being preferred embodiments within claims 15, 23, and 25 of the '220 patent.

[24] Claims 13-17 and 19-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7, 9-13, and 15 of US Patent 6,159,936 (the '936 patent). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759

F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 13 and 16 of the instant application is generic to all that is recited in claims 5-7, 9-13, and 15 of the '936 patent; claim 14 is generic to all that is recited in claims 6-7, 10 and 12-13 of the '936 patent; claim 17 is generic to all that is recited in claims 7 and 13 of the '936 patent; and claim 20 is generic to all that is recited in claim 15 of the '936 patent. That is, claims 13 and 16 of the instant application are anticipated by claims 5-7, 9-13, and 15 of the '936 patent; claim 14 is anticipated by claims 6-7, 10 and 12-13 of the '936 patent; claim 17 is anticipated by claims 7 and 13 of the '936 patent; and claim 20 is anticipated by claim 15 of the '936 patent. Alternatively, claims 15, 19, and 21 cannot be patentably distinct over claims 5 and 9 of the '936 patent when there is a specifically disclosed embodiment in the '936 patent that supports claims 5 and 9 of that patent and falls within the scope of claims 15, 19, and 21 herein because it would have been obvious to one of ordinary skill in the art to modify the methods of claims 5 and 9 by selecting a specifically disclosed embodiment that supports those claims, *i.e.*, the methods of claims 5 and 9 wherein the microbial infection is a bacteria recited in claims 15 or 19 of the instant application, and wherein the peptide is administered prophylactically (see columns 4 and 17 of the '936 patent). One of ordinary skill in the art would have been motivated to do this because those embodiments are disclosed as being preferred embodiments within claims 5 and 9 of the '936 patent.

[25] The examiner has made an earnest attempt to identify those patents and co-pending applications that claim overlapping subject matter for purposes of rejecting or

provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection, applicants should identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter, identify the corresponding claims of the instant application, and take the appropriate action, *e.g.,* cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection.

Citation of Relevant Prior Art

[26] The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Selsted et al. (*Infect Immun* 55:2281-2286). The reference of Selsted et al. teaches an arginine-rich guinea pig neutrophil defensin peptide having *in vitro* antimicrobial activity (see particularly pp. 2284-2285). However, the peptide of Selsted et al. does not meet all the limitations of the peptide claim 1 and thus cannot anticipate the method of claim 13. Further, the examiner can find no teachings in the prior art of record to modify the amino acid sequence of the peptide of Selsted et al. such that it is encompassed by the peptide of claim 1.

Conclusion

[27] Status of the claims:

- Claims 1-21 are pending.
- Claims 1-12 and 18 are withdrawn from consideration.
- Claims 13-17 and 19-21 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (571) 273-8300. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

02-02-05

David J. Steadman
Primary Examiner
Art Unit 1652

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